North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

HAND DELIVERED

NOTICE OF ADMINISTRATIVE ACTION
AMBULATORY SURGERY CENTER LICENSE

TO: **Lorraine Cummings, MD, Owner**
FEMCARE, Inc.
63 Orange Street
Asheville, NC 28801

FROM: **Azzie Y. Conley, RN**
Section Chief
Acute and Home Care Licensure and Certification Section

SUBJECT: **Summary Suspension of Your License to Operate**
Certificate No. AS0004

FID No. 943170

DATE: **July 31, 2013**

Pursuant to North Carolina General Statutes N.C.G.S. § 150B-3(c), the Division of Health Service Regulation (DHSR), North Carolina Department of Health and Human Services (DHHS), HEREBY SUMMARILY SUSPENDS YOUR CERTIFICATE TO OPERATE **FEMCARE, Inc.,** an ambulatory surgery facility. YOU ARE HEREBY DIRECTED TO CLOSE **FEMCARE, Inc.**, BY NO LATER THAN 5:00 O'CLOCK P.M. ON July 31, 2013.

AGENCY FINDINGS

This Summary Suspension is based on this agency's findings that conditions at FEMCARE, Inc., presents an imminent danger to the health, safety and welfare of the clients and that emergency action is required to protect the clients. This agency has identified the facility failed to be in substantial compliance with Rules for which they are licensed.

On July 18, 2013 through July 19, 2013, staff with the Acute and Home Care Licensure and Certification Section surveyed FEMCARE, Inc. Therefore, it is the finding of this agency that the facility has neglected to provide the services to assure the health, safety and welfare of the clients. As a result of the survey findings, the Section substantiated Rule violations that include:

- 10A NCAC 13C .0301(a) Governing Authority
- 10A NCAC 13C .0301(b) Governing Authority
- 10A NCAC 13C .0301(c) Governing Authority
- 10A NCAC 13C .0303(a) Administrative Records
- 10A NCAC 13C .0305(a) Personnel
- 10A NCAC 13C .0305(e) Personnel
- 10A NCAC 13C .0306(a) Quality Assurance
- 10A NCAC 13C .0306(b) Quality Assurance
- 10A NCAC 13C .0306(d) Quality Assurance
- 10A NCAC 13C .0401(b) Medical Services
- 10A NCAC 13C .0403(b) Emergency Cases
- 10A NCAC 13C .0502 Equipment
- 10A NCAC 13C .0801 Drug Dispensing
- 10A NCAC 13C .0901(a) Nursing Administration
- 10A NCAC 13C .0901(b) Nursing Administration
- 10A NCAC 13C .1101(c) Operating Suite
- 10A NCAC 13C .1201(a) General
- 10A NCAC 13C .1301 General
- 10A NCAC 13C .1302(a) Sterilization Procedures
- 10A NCAC 13C .1302(b) Sterilization Procedures
- 10A NCAC 13C .1302(c) Sterilization Procedures
- 10A NCAC 13C .1302(d) Sterilization Procedures
- 10A NCAC 13C .1303 Housekeeping

Review of survey findings revealed a potential imminent threat to the health and safety of patients. Based on the survey findings, the facility failed to have an organized and operational governing body. The facility failed to have policies and procedures current with standards of practice; failed to ensure anesthesia was administered to patients in a safe manner; failed to have a contract with an anesthetist; failed to have a contract with a pharmacist; failed to ensure staff were trained in the operations of the defibrillator to manage emergency situations, failed to have a Director of Nursing and organized nursing staff; failed to ensure staff were trained in infection control standards; failed to ensure equipment was appropriately sterilized and monitored; and failed to implement a quality improvement program.

Observations during the survey of July 18, 2013 through July 19, 2013, revealed facility staff failed to ensure the nitrous oxide gas delivery system was functioning appropriately. Observations revealed nasal masks used for the administration of nitrous oxide were torn and not intact, tubing was taped in layers at all connection sites, and no evidence of preventative maintenance on the nitrous oxide delivery system. The facility's failure to maintain a fully functioning nitrous oxide delivery system could affect the amount of the nitrous oxide delivered to the patient. Therefore, the patient would not receive the intended dosage of nitrous oxide medication as ordered by the physician for surgical abortion procedures. Thereby, the health, safety, and welfare of all patients is at risk of not being fully sedated during surgical procedures leading to pain and movement resulting in harm. Thereby, placing any patient who receives nitrous oxide at risk.

The Report of Survey upon which the agency's decision is based is enclosed.

During the onsite survey, deficiencies were identified and discussed with facility staff on July 19, 2013 and via telephone July 31, 2013. Therefore, it is the finding of this agency that the facility has neglected to provide the services to assure the health, safety and welfare of the patients.

APPEAL NOTICE

You have the right to contest this summary suspension of your certificate by filing a petition for a contested case hearing with the Office of Administrative Hearings (OAH) within sixty (60) days of your receipt of this letter. For complete instructions on the filing of petitions, please contact OAH at (919) 733-2698. The mailing address for OAH is as follows:

Office of Administrative Hearing
6714 Mail Services Center
Raleigh, NC 27699-6714

N.C.G.S. § 150B-23 provides that you must also serve a copy of the petition on all other parties, which includes DHHS. The Department's representative for such actions is Ms. Emery Edwards Milliken, General Counsel. This person may receive service of process by mail at the following address:

Ms. Emery Edwards Milliken, General Counsel
NC Department of Health and Human Services
Office of Legal Affairs
2005 Mail Service Center
Raleigh, NC 27699-2005

If you do not file a petition within the sixty (60) day period, you will lose your right to appeal this Summary Suspension. In addition to your right to file a petition for a contested case hearing, N.C. Gen. Stat. § 150B-22 encourages the settlement of disputes through informal procedures. In keeping with this law, this office remains readily available for discussion or other informal procedures to assist in resolving any dispute you may have with our findings and action. Please note that the use of informal procedures does not extend the sixty (60) days allowed to file for a contested case hearing as explained above.

Should you have any questions regarding any aspect of this letter, please do not hesitate to contact me at the Department of Health and Human Services, Division of Facility Services, Acute and Home Care Licensure and Certification Section, 2712 Mail Service Center, Raleigh, North Carolina 27699-2712 or contact me at (919) 855-4646.

cc: Drexdal Pratt, Director, Division of Facility Services
Cheryl Quimet, COO, Division of Facility Services
Emery Edwards Milliken, General Counsel, Department of Health and Human Services

File

STATE OF NORTH CAROLINA

COUNTY OF DURHAM

This Notice of Administrative Action, dated July 31, 2013, was hand delivered on July 31, 2013. The document was delivered in person by Paul D. William, MT, with the Acute and Home Care Licensure and Certification Section on July 31, 2013.

_____
Signature of Recipient

_____
Signature of Section Representative

_____
Date

Dr. Lorraine Cummings, Owner
FEMCARE, Inc.
July 31, 2013

STATE OF NORTH CAROLINA

COUNTY OF DURHAM

This Notice of Administrative Action, dated July 31, 2013, was hand delivered on July 31, 2013. The document was delivered in person by Paul D. William, MT, with the Acute and Home Care Licensure and Certification Section on July 31, 2013.

_____
Signature of Recipient

_____
Signature of Section Representative

_____
Date

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

VIA EMAIL

NOTICE OF INTENT TO REVOKE AMBULATORY SURGICAL FACILITY LICENSE

TO: **Dr. Lorraine Cummings, MD, Owner**
Femcare, Inc.
63 Orange Street
Asheville, NC 28801

FROM: **Azzie Y. Conley, RN**
Section Chief
Acute and Home Care Licensure and Certification Section

SUBJECT: **Intent to Revoke Your License to Operate**
AS0004

DATE: **July 26, 2013**

PROPOSED AGENCY ACTION

The North Carolina Department of Health and Human Services, Division of Health Service Regulation, Acute and Home Care Licensure and Certification Section, has determined that you have substantially failed to comply with the provisions of Article 6 Part 4 of Chapter §131E-145 of the North Carolina General Statute and the rules promulgated under that Part based on the survey conducted by the Licensure and Certification Section on July 18, 2013 through July 19, 2013. The Department, therefore, intends to revoke your Ambulatory Surgical Facility license. **This amendment is based on the facility's failure** to comply with the following:

- 10A NCAC 13C .0301(a) Governing Authority
- 10A NCAC 13C .0301(b) Governing Authority
- 10A NCAC 13C .0301(c) Governing Authority
- 10A NCAC 13C .0303(a) Administrative Records
- 10A NCAC 13C .0305(a) Personnel
- 10A NCAC 13C .0305(e) Personnel
- 10A NCAC 13C .0306(a) Quality Assurance
- 10A NCAC 13C .0306(b) Quality Assurance
- 10A NCAC 13C .0306(d) Quality Assurance
- 10A NCAC 13C .0401(b) Medical Services

•	10A NCAC	13C	.0403(b)	Emergency Cases
•	10A NCAC	13C	.0502	Equipment
•	10A NCAC	13C	.0801	Drug Dispensing
•	10A NCAC	13C	.0901(a)	Nursing Administration
•	10A NCAC	13C	.0901(b)	Nursing Administration
•	10A NCAC	13C	.1101(c)	Operating Suite
•	10A NCAC	13C	.1201(a)	General
•	10A NCAC	13C	.1301	General
•	10A NCAC	13C	.1302(a)	Sterilization Procedures
•	10A NCAC	13C	.1302(b)	Sterilization Procedures
•	10A NCAC	13C	.1302(c)	Sterilization Procedures
•	10A NCAC	13C	.1302(d)	Sterilization Procedures
•	10A NCAC	13C.	1303	Housekeeping

NOTICE OF OPPORTUNITY TO DEMONSTRATE COMPLIANCE WITH LICENSING LAWS AND RULES

Pursuant to N. C. General Statute §150B-3(b), you are hereby given an opportunity to show compliance with all lawful requirements for retention of your license to operate **Femcare, Inc.** If you believe that you have substantially complied with the licensure rules for ambulatory surgical facilities, you may submit a written statement to this agency. The statement should clearly set out all of the reasons showing that you contend compliance.

You may attach supporting documents to your statement. Send your written statement and any supporting documents to the attention of:

Azzie Conley, Section Chief
Division of Health Service Regulation Acute and Home Care
Licensure and Certification Section
2712 Mail Service Center
Raleigh, NC 27699-2712

In order to be considered, your written statement must be received by this agency within 10 calendar days after you receive this notice.

CONSEQUENCE OF FAILURE TO SUBMIT WRITTEN STATEMENT

If the agency does not receive a written statement from you within 10 calendar days after you receive this notice, the agency will revoke your license. If the agency receives a written statement within the time specified, the agency will carefully review the statement and any documents submitted with it. Following the review, the agency will decide to amend your license.

Any person aggrieved by this decision may file a petition for a contested case hearing in accordance with G.S. 150B, Article 3, as amended. This petition must be filed with the Office of Administrative Hearings, P.O. Drawer 27447 Raleigh, North Carolina 27611-7477 within sixty (60) days of receipt of this notice. G.S. 150-B-23 provides that a party filing a petition must also serve a copy of the petition on all parties to the petition. Therefore, if you file a petition for a contested case hearing, you must serve a copy of the petition on the Department of Health and Human Services by mailing a copy of your petition to:

Emery E. Milliken
General Counsel Office of Legal Affairs
Adams Building
Room 111
2005 Mail Service Center
Raleigh, NC 27699-2005

We will notify the appropriate agencies by copy of this letter. Please contact our office if there are any questions about this process.

Please contact **Debbie McCarty, Nurse Consultant at (919) 855-4620** or me should you have questions or need additional information regarding this notice or your right to show compliance with all lawful requirements for retention of your home care license.

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt, Director

July 26, 2013

Lorraine Cummings, M.D., Owner
Femcare, Inc
63 Orange Street
Asheville, NC 28801

Re: Licensure Survey

Dear Dr. Cummings,

Thank you and your staff for the assistance and cooperation extended during the licensure survey at Femcare, Inc in Asheville, NC from July 18, 2013 through July 19, 2013. The investigation was conducted in order to determine the facility's compliance with the NC Rules Governing the Licensure of Ambulatory Surgical Facilities.

As discussed in the exit conference, deficiencies were identified in the area of 10A NCAC 13C NC Rules Governing the Licensure of Ambulatory Surgical Facilities.

Enclosed please find CMS Form 2567, "Statement of Deficiencies and Plan of Correction," containing the cited deficiencies. A plan of correction for the deficiencies must be submitted and should include the following:

(a) A description of the corrective action(s) and the systems that have been or will be implemented to correct the deficiency.
(b) A description of the monitoring system that has been or will be implemented
(c) The date by which all corrective actions will be completed and the monitoring

An ***original*** of the enclosed form CMS 2567, with the plan of correction added, **must be returned to this office, SIGNED AND DATED, WITHIN 10 CALENDAR DAYS OF RECEIPT. We are unable to accept e-mailed or faxed reports at this time.** A response will be sent ONLY if the plan of correction is not approved. Please retain a copy for your files. If you have any questions, please feel free to contact me by calling (919) 855-4620.

Sincerely,

Debbie McCarty, RN

Debbie McCarty, RN
Nurse Consultant
Acute and Home Care Licensure and Certification Section

Enclosures: State Form Statement of Deficiencies

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 000	INITIAL COMMENTS An unannounced licensure survey was conducted on July 18, 2013 through July 19, 2013. Based on the survey findings, violations of the rules were identified. The facility failed to follow standard infection control practices as recommended by Centers for Disease Control and Prevention. Review of the CDC (Centers for Disease Control and Prevention) guidelines for the sterilization of surgical instruments revealed the sterilization procedure should be monitored routinely by using a combination of mechanical, chemical, and biological indicators to evaluate the sterilizing conditions and indirectly the microbiologic status of the processed items. Survey findings revealed no mechanical, chemical, and biological indicators were used for monitoring the sterilization process. The failure to ensure proper sterilization of surgical instruments could result in infections. Pursuant to North Carolina General Statutes N.C.G.S. § 150B-3(c), the Division of Health Service Regulation (DHSR), North Carolina Department of Health and Human Services (DHHS), HEREBY INTENDS TO REVOKE THE LICENSE TO OPERATE FEMCARE, INC., an ambulatory surgical facility.	Q 000		
Q 111	.0301(A) GOVERNING AUTHORITY 10A-13C.0301 (a) The facility's governing authority shall adopt bylaws or other appropriate operating policies and procedures which shall: (1) specify by name the person to whom responsibility for operation and maintenance of the facility is delegated and methods established by	Q 111		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 111	Continued From page 1 the governing authority for holding such individuals responsible; (2) provide for at least annual meetings of the governing authority if the governing authority consists of two or more individuals. Minutes shall be maintained of such meetings; (3) maintain a policies and procedures manual which is designed to ensure professional and safe care for the patients. The manual shall be reviewed, and revised when necessary, at least annually. The manual shall include provisions for administration and use of the facility, compliance, personnel quality assurance, procurement of outside services and consultations, patient care policies and services offered; and (4) provide for annual reviews and evaluations of the facility's policies, management, and operation. This Rule is not met as evidenced by: Based on review of the facility's policies and procedures and physician interview, the governing authority failed to ensure annual review of policies was conducted. The findings include: Review of the facility's policies and procedure manual on 07/18/2013 revealed the most recent review of policies was March 1990. Interview on 07/19/2013 at 1440 with Physician A (owner) revealed the physician was a solo practice and she was the governing authority for the facility. The physician interview revealed there were a number of policies that were not	Q 111		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 111	Continued From page 2 current and did not represent current practice. Interview confirmed March 1990 was the last review of the facility policies.	Q 111		
Q 112	.0301(B) GOVERNING AUTHORITY 10A-13C.0301 (b) When services such as dietary, laundry, or therapy services are purchased from others, the governing authority shall be responsible to assure the supplier meets the same local and state standards the facility would have to meet if it were providing those services itself using its own staff. This Rule is not met as evidenced by: Based on observation during tour of the facility, review of agreements and staff and physician interviews, the facility's governing authority failed to ensure oversight of housekeeping services. The findings include: Review of a "Cleaning Contract" signed 08/05/2003 revealed "Tuesday: ...Wipe down bottom or operating room beds; ... Sweep entire building; hallways, bathrooms, exam rooms, kitchen and operating room area; ... Mop entire building with germicide; ... Miscellaneous indoor cleaning: ...Wipe down walls in operating rooms every other week; Dust and clean light fixtures bi-monthly or as needed." Observation on 07/15/2013 at 1740 during tour of the operating room #1 revealed a thick layer of dust that rolled up when touched that was covering the top of the crash cart that was located in the operating room (OR). Observation further	Q 112		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 112	Continued From page 3 revealed a thick layer of dust on the surface of the suction machine and nitrous oxide machine located in the OR. Observation revealed a thick layer of dust located on the surface of the suction machine and nitrous oxide machine in OR #2. Physician A confirmed the observation. Interview on 07/19/2013 at 0907 with staff #3 (non-licensed staff) revealed the facility staff clean between patients including wiping down the operating room beds and any blood spills. Interview revealed the staff do not mop floors between patients. Interview revealed surgical procedures are scheduled on Wednesdays, Fridays and Saturdays. The staff member stated there was a person that comes to the facility on Tuesday evenings that does the "big cleaning" including mopping. Staff #3 stated housekeeping comes on Wednesday and Friday evenings, but the staff member was unsure if the floors are mopped on those days. Interview on 07/19/2013 at 1440 with Physician A revealed the physician did not know if terminal cleaning of the operating rooms was being done. Interview revealed the physician did not know how often floors were being mopped in the operating rooms. Interview confirmed there was no documentation of terminal cleaning of the operating rooms and no monitoring of housekeeping duties. Interview confirmed there was a think layer of dust located on the equipment and horizontal surfaces in the operating rooms. Interview revealed the physician did not know if the housekeeping staff had any training in infection control prevention.	Q 112		
Q 113	.0301(C) GOVERNING AUTHORITY	Q 113		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 113	Continued From page 4 10A-13C.0301 (c) The governing authority shall provide for the selection and appointment of the professional staff and the granting of clinical privileges and shall be responsible for the professional conduct of these persons. This Rule is not met as evidenced by: Based on policy review, credentialing file review and physician interview, the governing authority failed to ensure privileges were delineated for 1 of 1 physician files reviewed (Physician A). The findings include: Review of "Quality Assurance Guidelines" policy revised April 2002 revealed "A committee composed of (name of two physicians and a certified nurse midwife) shall meet quarterly to review the policies, appropriateness of procedures, quality of care rendered in the outpatient surgical facility, tissue review, establish infection control and approve additional services. All staff members of the surgical facility shall be board certified or qualified in Obstetrics and Gynecology. They will be a member of the active staff of (local hospital)." Further review revealed a procedure that included "10. Credentials will be reviewed every two years consistent with the hospital protocols." Review of Physician A's file revealed a "Request for Privileges" form with blanks to check "requested" and "granted" privileges. The procedures listed included "first and second trimester abortion (Dilitation and suction evacuation); sterilization via laproscopy both cautery and clips; and ultrasounding." Further review of the form revealed "Completed by	Q 113		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 113	Continued From page 5 Physician" and "Completed by Medical Director" both signed by Physician A and dated 07/01/2013. Further review of the form revealed the "Procedures requested and granted" were blank with no checks indicating which procedures were requested and approved. Interview on 07/19/2013 at 0905 with Physician A revealed there was no quality assurance committee and no process for reappointment or granting privileges. Interview revealed the physician was a solo practice and she just signed the form as requesting and approving privileges. The physician reviewed the form and immediately checked the requested and granted privileges as approved. Physician A confirmed the procedures requested and approved was blank and stated she forgot to check the procedures.	Q 113		
Q 115	.0303 ADMINISTRATIVE RECORDS 10A-13C.0303 (a) The following essential documents and references shall be on file in the administrative office of the facility: (1) appropriate documents evidencing control and ownerships, such as deeds, leases, or corporation or partnership papers; (2) bylaws of policies and procedures of the governing authority; (3) minutes of the governing authority meetings if applicable; (4) minutes of the facility's professional and administrative staff meetings; (5) a current copy of these regulations; (6) reports of inspections, reviews,	Q 115		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 115	Continued From page 6 and corrective actions taken related to licensure; and (7) contracts and agreements related to licensure to which the facility is a party. (b) All operating licenses, permits and certificates shall be appropriately displayed on the licensed premises. This Rule is not met as evidenced by: Based on review of facility policies and procedures, meeting minutes and physician interview, the facility failed to maintain evidence of bylaws of the governing authority, minutes of governing authority meeting minutes or staff meeting minutes and failed to have a current copy of the NC Rules Governing the Licensure of Ambulatory Surgical Facilities. The findings include: Review of facility policies and meeting minutes revealed no evidence of governing authority bylaws, governing authority meeting minutes or staff meeting minutes for the past year. Further review revealed no current copy of the NC Rules Governing the Licensure of Ambulatory Surgical Facilities. Interview on 07/19/2013 at 1420 with the physician and owner of the facility (Physician A) revealed there was no governing authority meeting as she was a solo practioner. Interview revealed there were no staff meetings and no meeting minutes. The physician stated there may have been some bylaws years ago, but she was not aware of any bylaws that could be provided. The physician stated "They (the bylaws) might have been in another book, but I think I threw that	Q 115		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 115	Continued From page 7 book out. I am not really sure." The physician stated she did not have a copy of the NC Rules Governing the Licensure of Ambulatory Surgical Facilities.	Q 115		
Q 117	.0305(A) PERSONNEL 10A-13C.0305 (a) Personnel Records (1) A record of each employee shall be maintained which includes the following: (A) employee's identification; (B) resume of education and work experience; (C) verification of valid license (if required), education, training, and prior employment experience; and (D) verification of references. (2) Personnel records shall be confidential. (3) Notwithstanding the requirement found in Subparagraph (a)(2) of this Rule, representatives of the Department conducting an inspection of the facility shall have the right to inspect personnel records. This Rule is not met as evidenced by: Based on personnel file review and staff and physician interview, the facility failed to have a personnel file for 1 of 5 employee files reviewed (staff #4). The findings include: Interview on 07/19/2013 at 0907 with staff #3 (non-licensed) revealed she was the person that was processing (sterilizing) the surgical instruments. Interview revealed staff #3 did not	Q 117		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 117	Continued From page 8 usually process the surgical instruments and was filling in for the regular person who was on vacation. Interview revealed the regular person that processed the surgical instruments was a volunteer (staff #4). Interview revealed staff #4 (volunteer) had been processing the instruments for about a year. Interview revealed staff #3 had been trained by staff #4 regarding how to process the instruments. Review revealed there was no personnel file and no evidence of training or competency checks regarding processing surgical instruments for staff #4. Review revealed there was no evidence of the volunteer employee's application, resume, prior work history and verification of references available. Interview on 07/19/2013 at 1430 with Physician A revealed staff #4 was a volunteer and there was no personnel file for staff #4. The physician stated there was no application, resume, work history or verification of references available for staff #4. Interview confirmed the job responsibilities for staff #4 included processing the surgical instruments. Interview revealed staff #4 had no medical background and had not processed surgical instruments prior to volunteering at this facility. Interview revealed staff #4 was trained to process surgical instruments by a former employee. Interview confirmed there was no evidence of training or competency checks available.	Q 117		
Q 119	.0305(C)(D)(E) PERSONNEL 10A 13C .0305 (c) Orientation shall be provided to familiarize each new employee with the facility, its	Q 119		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 119	Continued From page 9 policies, and job responsibilities. (d) All persons having direct responsibility for patient care shall be at least 18 years of age. All other employees working in the facility shall be not less than 16 years of age. (e) The governing authority shall be responsible for insuring health standards for employees which are consistent with recognized professional practices for the prevention and transmission of communicable diseases. This Rule is not met as evidenced by: Based on review of facility policies, employee file review and physician interview, the governing authority failed to establish written protocol for health standards for employees. The findings include: Review of facility policies revealed no policy or procedure that established guidelines for employee health. Review of employee files revealed TB testing or screening was not completed in the past year for 1 of 2 RN files reviewed (RN #1). Interview on 07/19/2013 at 1430 with Physician A revealed there were no policies established regarding surveillance of communicable diseases such as TB and hepatitis in employees. Interview revealed TB testing or screening should be conducted annually for all employees. The physician confirmed RN #1's TB testing had not been completed within the past year and was delinquent.	Q 119		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 120	Continued From page 10	Q 120		
Q 120	.0306 QUALITY ASSURANCE 10A-13C.0306 (a) The governing authority shall establish a quality assurance program for the purpose of providing standards of care for the facility. The program shall include the establishment of a committee which shall evaluate: (1) appropriateness and necessity of surgical procedures performed, and (2) compliance with facility procedure and policies. The committee shall determine corrective action if indicated. (b) The committee shall consist of at least one physician or dentist (who is not an owner), the chief executive officer (or his designee), and other health professionals as indicated. There shall be at least one meeting of the committee quarterly. (c) The functions of the committee shall include development of policies for selection of patients, review of credentials for staff privileges, peer review, tissue review, establishment of infection control procedures, and approval of additional surgical procedures to be performed in the facility. (d) Records shall be kept of the activities of the committee. These records shall include as a minimum: (1) reports made to the governing authority; (2) minutes of committee meetings including date, time, persons attending, description and results of	Q 120		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 120	Continued From page 11 cases reviewed, and recommendations made by the committee; and (3) information on any corrective action taken. (e) Appropriate orientation, training or education programs shall be conducted as necessary to correct deficiencies which are uncovered as a result of the quality assurance program. This Rule is not met as evidenced by: Based on review of policy, quality assurance meeting minutes and physician interview, the governing authority failed to have a quality assurance program. Review revealed no monitoring of the quality of care and services provided, no evidence of meeting minutes and no evidence of a non-physician owner present on a quality committee. The findings include: Review of "Quality Assurance Guidelines" policy revised April 2002 revealed "A committee composed of (name of two physicians and a certified nurse midwife) shall meet quarterly to review the policies, appropriateness of procedures, quality of care rendered in the outpatient surgical facility, tissue review, establish infection control and approve additional services. All staff members of the surgical facility shall be board certified or qualified in Obstetrics and Gynecology. They will be member of the active staff of (local hospital)." Further review revealed a procedure that included review of sampled medical records for procedures that are performed at the facility including complications. The procedure includes "10. Credentials will be reviewed every two years consistent with the	Q 120		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 120	Continued From page 12 hospital protocols." Review of the facility's quality assurance (QA) committee meeting minutes revealed the most recent QA meeting was January 25, 2007. Interview on 07/19/2013 at 1440 with Physician A revealed there was not a QA committee and there had not been any quality reviews of medical records since 2007. Interview confirmed there was not a non-owner physician member that was part of a QA committee. Interview with the physician confirmed there was no QA program or functions in place currently or since 2007.	Q 120		
Q 121	.0401 MEDICAL SERVICES 10A-13C.0401 (a) All patients admitted to the facility shall be under the direct care of a physician or dentist. (b) The facility shall have available an anesthetist and he or she shall be available to administer regional or general anesthesia. (c) Any patient undergoing general or regional anesthesia shall, prior to surgery, have a history and physical examination, relative to the intended procedure, performed by a licensed physician or a dentist who has successfully completed a postgraduate program in oral and maxillofacial surgery accredited by the American Dental Association. Results of the examination and the preoperative diagnosis shall be recorded in the patient's chart prior to surgery. (d) The attending physician and dentist, prior to surgery, shall	Q 121		

STATEMENT OF DEFICIENCIES ANO PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IOENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET AODRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) IO PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDEO BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIOER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE OEFICIENCY)	(X5) COMPLETE DATE
Q 121	Continued From page 13 obtain written, informed consent of the patient or legal guardian for surgery and shall record this in the patient's medical record. (e) The facility shall have the capability of obtaining blood and blood products to meet emergency situations. This Rule is not met as evidenced by: Based on review of the facility's contracted services and physician interview, the facility failed to have an anesthetist available. The findings include: Review of the facility's contracted services on 07/19/2013 revealed no agreement and/or contract for anesthesia services. Interview on 07/19/2013 at 1430 with Physician A revealed the facility does not currently have an agreement and/or contract with an anesthetist or anesthesiologist. The interview revealed the physician was not aware of the requirement.	Q 121		
Q 123	.0403 EMERGENCY CASES 10A-13C.0403. (a) Each facility shall have a written plan for the transfer of emergency cases to a nearby hospital when hospitalization becomes necessary. (b) There shall be procedures, personnel and suitable equipment to handle medical emergencies which may arise in connection with services provided by the facility. (c) There shall be a written	Q 123		

STATEMENT OF DEFICIENCIES ANO PLAN OF CORRECTION	(X1) PROVIOER/SUPPLIER/CLIA IOENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) OATE SURVEY COMPLETED
	20130055	A. BUILOING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET AODRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF OEFICIENCIES (EACH DEFICIENCY MUST BE PRECEOEO BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIOER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULO BE CROSS-REFERENCED TO THE APPROPRIATE OEFICIENCY)	(X5) COMPLETE DATE
Q 123	Continued From page 14 agreement between the facility and a nearby hospital to facilitate the transfer of patients who are in need of emergency care. A facility which has documentation of its efforts to establish such a transfer agreement with a hospital which provides emergency services and has been unable to secure such an agreement shall be considered to be in compliance with this Rule. This Rule is not met as evidenced by: Based on policy review, observation and staff and physician interviews, the facility failed to ensure emergency equipment had weekly checks performed according to policy to ensure the equipment was suitable for use in patient care. The findings include: Review of "Emergency Preparedness and Equipment" policy dated as revised January 1989 revealed "Must be available and in working order at all times the following: ...8. Suction machine with clean suctiDn catheter #18... 12. Defibrillator..." Review of a "Crash Cart" policy revised 1990 revealed crash cart drugs and equipment are to be checked weekly. Review of "Nursing Policy Responsibilities in the Operating Room" (not dated) revealed "The LPNs and RNs will be responsible for functions in the operating room. ... They will perform the following responsibilities: ...8. Check the crash cart each surgery day prior to the initiation of the procedures."	Q 123		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 123	Continued From page 15 Observation during tour of the operating room on 07/18/2013 at 1545 revealed a crash cart with a Medtronic Physio-Control LifePac 9 defibrillator located on top of the crash cart. Observation revealed medication and supplies on the crash cart were not secured with a locking mechanism. Interview with Physician A during the tour revealed there was no log or evidence of dates when the crash cart medications and equipment were checked. Interview revealed the defibrillator was not checked by staff to verify it was functioning properly. Interview with the physician revealed she was not aware of the need to check the defibrillator periodically. The interview revealed the facility had a user manual for the defibrillator. Review of the user manual for the Physio-Control LifePac 9 defibrillator revealed "Section 7 Maintaining the Equipment" was missing from the manual. Further observation revealed a suction machine on top of the crash cart. Interview revealed staff did not check the suction machine for proper functioning. Interview on 07/19/2013 at 1045 with staff #2 (registered nurse) revealed the nurse did not check the crash cart. The nurse stated "I do not know how to do a defibrillator check or trouble shoot the machine. I do not do checks." Interview on 07/19/2013 at 1115 with staff #1 (registered nurse) revealed the nurse did not perform any monitoring of the crash cart to ensure medications, supplies and equipment were not expired, available and in working order when needed. Interview revealed the nurse did not know the procedure to perform checks on the defibrillator to ensure it was functional. Interview on 07/19/2013 at 1430 with Physician A revealed there was no process in place to check	Q 123		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 123	Continued From page 16 the defibrillator and suction machine on the crash cart to ensure there were in working order when needed. The physician confirmed the defibrillator had not been checked according to manufacturer's recommendations. Interview confirmed the physician was not sure how to perform the defibrillator checks and the manufacturer's user manual was missing the section that provided guidance with maintaining the equipment. Review of "Medtronic Physio-Control LifePac 9 User Manual Section 7 Maintaining the Equipment" obtained via computer search by facility staff after requested by surveyor on 07/19/2013 revealed "... Physio-Control recommends a minimum program of routine maintenance and testing for clinical personnel. ... Recommended maintenance and testing for clinical personnel: Check all necessary supplies and accessories are present (gel, paper, cables, electrodes, etc.) daily and whenever necessary; Operational tests, monitor function, defibrillator/sync discharge function with standard paddles, adaptors or paddle options daily and whenever necessary; Verify paddles are clean daily.... Additional preventative maintenance and testing such as electrical safety tests, performance testing and calibration should be performed routinely by biomedical personnel...."	Q 123		
Q 125	.0502 EQUIPMENT 10A-13C.0502 All equipment for the administration of anesthetics shall be readily available, kept clean or sterile, and maintained in good working condition.	Q 125		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 125	Continued From page 17 This Rule is not met as evidenced by: Based on medical record review, observation and staff and physician interview, the nitrous oxide gas delivery systems were not maintained in good working condition. The findings include: Closed record review of 16 patients that had surgical abortion procedures performed between January 2013 and July 2013 revealed 100% (all 16 patients) had nitrous oxide gas administered at a 30% nitrous oxide, 70% oxygen mix as per the facility's standing orders. Observation on 07/18/2013 at 1805 revealed a nitrous oxide delivery system in OR #1. Observation revealed tubing was taped at all connections with layers of tape. Observation revealed the tubing was taped with layers of tape where the tubing connected to the wall oxygen, where two tubes connected to the delivery control machine, where tubing connected to the nasal mask and where the reservoir bag connected to the system. Observation revealed the nasal mask was torn down the center. Observation of OR #2 revealed another nitrous oxide delivery system. Observation revealed tubing was taped at all connections with layers of tape just as it was observed in OR #1. Observation revealed the nasal mask was torn down the center. Observation on 07/19/2013 at 1620 revealed the tape had been removed by facility staff on the tubing that connected the nasal mask to the nitrous oxide delivery system in OR #1. Observation revealed the tubing was gaping open after the tape was removed.	Q 125		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 125	Continued From page 18 Interview on 07/19/2013 at 1045 with staff #2 (registered nurse) revealed the nurse assisted Physician A in the operating room and was responsible for administering the nitrous oxide during the surgical procedure. The nurse stated staff #1 had trained her on the use of the nitrous oxide gas. Interview revealed the nurse did not check the nitrous oxide machine or hoses for leaks. Interview revealed the nitrous oxide tubing is taped between the connections and the nasal mask has a large tear across the top that prevents the mask from making a secure fit. Interview on 07/19/2013 at 0907 with staff #3 (non-licensed staff) revealed there had not been any maintenance checks on the nitrous oxide machines in the last nine years. Interview revealed the hoses had not been replaced in nine years. The staff member stated she did not remember the nose mask ever being replaced. Interview on 07/19/2013 at 1115 with staff #1 (registered nurse) revealed she did not know what the manufacturer's recommendations for maintenance and safety checks were for the nitrous oxide delivery system. The staff member stated "I'm not doing any checks and I do not know what the recommendation are." The nurse further stated "The hose is cracked where we have it taped. The nasal mask is ripped. It should be replaced." Further interview revealed the nitrous oxide machine has not had any preventative maintenance performed. Physician interview during tour on 07/18/2013 at 1805 revealed there was no users guide for the nitrous oxide delivery system. Interview revealed no preventative maintenance had been performed on the equipment. The physician	Q 125		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 125	Continued From page 19 stated "We have cracks. We need new (nitrous oxide) tubing. I don't know if it is leaking or not. I can't be sure it is functioning with the proper mix. I have not had it tested." Further interview on 07/19/2013 at 1500 with Physician A revealed "Yes, there must be a better system. We don't know if the nitrous oxide is leaking or if the patient is getting the correct amount of gas. Yes, it (the tubing and nasal mask) is cracked and the taped tubes are not a safe way to do this."	Q 125		
Q 132	.0801 DRUG DISPENSING 10A-13C.0801 The governing authority, with the advice of a registered pharmacist, shall assure that there are appropriate methods, procedures and controls for obtaining, dispensing, and administering drugs and biologicals. This Rule is not met as evidenced by: Based on contract reviews and physician interview the facility leadership failed to have a contract or written agreement with a registered pharmacist to assure appropriate methods, procedures and controls for obtaining, dispensing, and administering drugs and biologicals are being implemented by the staff. The findings include: On 07/18/2013 at 0930, a request was made to the facility administration to provide a list of all contracts related to patient care services. Review of the contracts revealed no available documentation of a written contract or agreement between the ambulatory surgical center and a registered pharmacist for providing advice to the	Q 132		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 132	Continued From page 20 facility to assure appropriate methods, procedures and controls for obtaining, dispensing, and administering drugs and biologicals are being implemented by the facility staff. Observation on 07/19/2013 at 1120 of medications revealed prepared envelopes of medication envelopes labeled "Methergine 0.2 mg (milligram)." Interview with staff during tour revealed the medication was labeled and packaged by facility staff and dispensed by the physician. Interview with staff confirmed the medication was taken from larger bottles of the pills and placed in the packets. Interview confirmed the label did not have a lot number and expiration date on the envelope. Interview on 07/19/2013 at 1510 with Physician A revealed the facility does not have a registered pharmacist on staff. Further interview revealed the facility does not have a written contract or agreement with a registered pharmacist to provide consultation to the facility. Interview revealed a registered pharmacist does not provide oversight or perform periodic audits/visits at the facility. Interview revealed the medical director was over the pharmaceutical services provided at the facility..	Q 132		
Q 134	.0901 NURSING ADMINISTRATION 10A-13C.0901 (a) The facility shall have an organized nursing Department under the supervision of a director of nursing who is currently licensed as a registered nurse and who has responsibility and accountability for all nursing services.	Q 134		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 134	Continued From page 21 (b) The director of nursing shall be responsible and accountable to the chief executive officer for: (1) provision of nursing services to patients; (2) developing a nursing policy and procedure manual and written job descriptions for nursing personnel. This Rule is not met as evidenced by: Based on review of job description, personnel files and staff and physician interview, the facility failed to have a director of nursing responsible and accountable for all nursing services. The findings include: Review of a "Job Description for Director of Nursing" (not dated) revealed "The Director of Nursing must be a registered nurse in the State of North Carolina. The Director of Nursing will report directly to the Medical Director... responsibilities: 1. She will oversee and direct all nursing functions in (facility name). 2. ...Assign duties and responsibilities on surgery days... 3. She will be responsible for training new RNs and new LPNs in (facility name) protocols and record such training in personnel files. 4. She will be responsible to see that the crash carts and portable oxygen units are functioning. 5. She will attend Quality Assurance meetings. 6. She will inventory medical supplies and needs and submit for ordering..." Review of the personnel files for staff #1 and staff #2 (registered nurses currently on staff at the facility) revealed no evidence the registered nurses (RNs) were identified as a Director of Nursing position. Review revealed staff #1 and staff #2 files contained staff RN job descriptions.	Q 134		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 134	Continued From page 22 Interview on 07/19/2013 at 1115 with staff #1 (registered nurse) revealed the staff member is a registered nurse (RN) that has worked at the facility since 2003. Interview revealed all staff report to Physician A. Interview further revealed that a Certified Nurse Midwife (CNM) was the director of nursing a couple of years ago. Interview revealed the CNM currently examines patients for gynecological appointments one day a week in the office practice and is not involved with any surgical procedures. Interview on 07/19/2013 at 1045 with staff #2 (registered nurse) revealed there was no director of nursing and all staff reported to Physician A. Interview on 07/19/2013 at 0907 with staff #3 (non-licensed staff) revealed there was not a director of nursing. Interview revealed the staff member reported directly to Physician A. Interview on 07/19/2013 at 1545 with Physician A revealed the physician functions in the role of the director of nursing and all the facility staff report to the physician. Interview revealed the CNM was the director of nursing in the past. Interview revealed the facility staff all report directly to Physician A. Interview confirmed there had not been a director of nursing for over a year.	Q 134		
Q 139	.1101 OPERATING SUITE 10A-13C.1101 (a) Each operating suite shall be adequately equipped for the types of procedures to be performed. (b) Each recovery area shall be adequately equipped for the proper care of post anesthesia recovery of	Q 139		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 139	Continued From page 23 surgical patients. (c) The following equipment shall be available in the operating suite and recovery area: (1) cardio-pulmonary resuscitation drugs and intubation equipment, (2) cardiac monitor, (3) resuscitator including oxygen and suction equipment, (4) suitable surgical instruments customarily available for the planned surgical procedure, (5) defibrillator, and (6) tracheostomy set. This Rule is not met as evidenced by: Based on observation and physician interview, the facility failed to have a resuscitator available. The findings include: Observation during tours of the facility on 07/18/2013 at 1730 revealed there was no resuscitator available for use. Interview on 07/18/2013 at 1730 with Physician A during the tour confirmed there was no resuscitator available. Interview revealed the physician was not aware that a resuscitator was required.	Q 139		
Q 141	.1201 GENERAL 10A-13C.1201 (a) The governing authority shall develop written policies and procedures designed to enhance safety within the facility and on its grounds and minimize hazards to patients, staff and visitors.	Q 141		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 141	Continued From page 24 (b) The policies and procedures shall include establishment of the following: (1) safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs; (2) provisions for reporting and the investigation of accidental events regarding patients, visitors and personnel (incidents) and corrective action taken; (3) provision for dissemination of safety-related information to employees and users of the facility; and (4) provision for syringe and needle storage, handling and disposal. (c) Smoking shall be permitted only in designated areas which shall not include patient care and treatment areas. This Rule is not met as evidenced by: Based on policy reviews, observation, staff and physician interviews, the facility failed to ensure fire safety drills were conducted. The findings include: Review of a "Fire Plan" policy revised 1989 revealed the facility should conduct fire drills quarterly. Review of the facility's "Fire Drills and Fire Alarm System" log revealed the most recent fire drill was conducted May 25, 2011. Interview on 07/19/2013 at 0907 with staff #3 (non-licensed staff) revealed there had not been any fire drills conducted in several years.	Q 141		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 141	Continued From page 25 Interview on 07/19/2013 at 1045 with staff #2 (registered nurse) revealed the nurse had worked at the facility for one and one half years. The staff member stated she had never participated in a fire drill since she had worked at the facility. Interview on 07/19/2013 at 115 with staff #1 (registered nurse) revealed no fire drills had been conducted at the facility in the past two years. Interview on 07/19/2013 at 1545 with Physician A confirmed the last fire drill conducted at the facility was May 25, 2011.	Q 141		
Q 144	.1301 GENERAL 10A 13C .1301 The governing authority shall employee procedures to minimize sources and transmission of infections. Professionally recognized surveillance methods shall be used. The governing authority shall provide space, equipment and personnel to assure safe and aseptic treatment and protection of all patients and personnel against cross-infection. This Rule is not met as evidenced by: Based on review of policies, culture results, meeting minutes, Centers for Disease Control and Prevention (CDC) guidelines, observation and staff and physician interviews, the facility failed to have an active infection control program. The findings include: Review of an "Infection Control" policy revised 1992 revealed infection control policies are established and reviewed by the Quality	Q 144		

STATEMENT OF OEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIOER/SUPPLIER/CLIA IOENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADORESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 144	Continued From page 26 Assurance Committee. Review revealed patients identified with communicable diseases and employee exposures are to be tracked and reported. Further review of the policy revealed the operative sterile trays are to be cultured annually. Operating room floors are to be mopped daily and walls cleaned bi-weekly. Review of the most recent result of a cultured sterile tray revealed a negative growth report dated 2011. Review of facility documents revealed no evidence of infection control monitoring or meeting minutes. 1, Review of "Operating of Pelton and Crane Autoclave" policy revised January 1989 revealed a procedure for steam sterilization of surgical instruments. Review of the policy revealed no procedure for the use of chemical or biological indicators during the sterilizing process. Review of the CDC (Centers for Disease Control and Prevention) Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008; Healthcare Infection Control Practices Advisory Committee (HICPAC) revealed "Sterilizing Practices Overview. The delivery of sterile products for use in patient care depends not only on the effectiveness of the sterilization process but also on the unit design, decontamination, disassembling and packaging of the device, loading the sterilizer, monitoring, sterilant quality and quantity, and the appropriateness of the cycle for the load contents, and other aspects of device reprocessing. ...Ensuring consistency of sterilization practices requires a comprehensive program that ensures operator competence and proper methods of cleaning and wrapping	Q 144		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 144	Continued From page 27 instruments, loading the sterilizer, operating the sterilizer, and monitoring of the entire process. ...Monitoring. The sterilization procedure should be monitored routinely by using a combination of mechanical, chemical, and biological indicators to evaluate the sterilizing conditions and indirectly the microbiologic status of the processed items. ... Chemical indicators are convenient, are inexpensive, and indicate that the item has been exposed to the sterilization process. Chemical indicators should be used in conjunction with biological indicators, but based on current studies should not replace them because they indicate sterilization at marginal sterilization time and because only a biological indicator consisting of resistant spores can measure the microbial killing power of the sterilization process847, 974. Chemical indicators are affixed on the outside of each pack to show that the package has been processed through a sterilization cycle, but these indicators do not prove sterilization has been achieved. Preferably, a chemical indicator also should be placed on the inside of each pack to verify sterilant penetration. ...Like other sterilization systems, the steam cycle is monitored by mechanical, chemical, and biological monitors. Steam sterilizers usually are monitored using a printout (or graphically) by measuring temperature, the time at the temperature, and pressure. Typically, chemical indicators are affixed to the outside and incorporated into the pack to monitor the temperature or time and temperature. The effectiveness of steam sterilization is monitored with a biological indicator containing spores of Geobacillus stearothermophilus (formerly Bacillus stearothermophilus). Positive spore test results are a relatively rare event 838 and can be attributed to operator error, inadequate steam delivery 839, or equipment malfunction. ...Sterile	Q 144		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 144	Continued From page 28 items that become wet are considered contaminated because moisture brings with it microorganisms from the air and surfaces...". Further review of the guidelines revealed "16. Monitoring of Sterilizers ...b. Monitor each load with mechanical (e.g., time, temperature, pressure) and chemical (internal and external) indicators. If the internal chemical indicator is visible, an external indicator is not needed. ... d. Use biological indicators to monitor the effectiveness of sterilizers at least weekly with an FDA-cleared commercial preparation of spores (e.g., Geobacillus stearothermophilus for steam) intended specifically for the type and cycle parameters of the sterilizer...." Observation on 07/18/2013 at 1810 during tour of the facility's sterile processing area revealed a ceiling tile (drop down ceiling) that was missing above the autoclave area where clean sterile packs were processed. The area was open to the pipes and air flow above the ceiling. Observation of the top of the autoclave revealed excessive dust that rolled up when touched. Interview during the tour with Physician A revealed the facility had a leak last week and the tile had to be removed. Interview confirmed the top of the autoclave was covered with a layer of dust. Observation on 07/18/2013 at 1815 revealed a cart with instrument packs located on the cart. Interview with Physician A during the tour revealed these packs were sterilized and available for use. Observation revealed three packs with beads of moisture located inside the clear packs. Physician A stated "Yes, there is condensation inside the packs. It will be okay tomorrow. I don't think there is a problem with that."	Q 144		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 144	Continued From page 29 Interview on 07/19/2013 at 0907 with staff #3 (non-licensed staff) revealed she was the person that was processing (sterilizing) the surgical instruments. Interview revealed staff #3 did not usually process the surgical instruments and was filling in for the regular person who was on vacation. Interview revealed the regular person that processed the surgical instruments was a volunteer (staff #4). Interview revealed staff #4 (volunteer) had been processing the instruments for about a year. Interview revealed staff #3 had been trained by staff #4 regarding how to process the instruments. Further interview revealed the staff member stated she "pulled the instruments out of the autoclave too early yesterday and caused the condensation." The staff member stated she was not aware that it was a problem to remove the packs before the drying cycle was completed and she was trying to get all of the packs done. Staff #3 revealed there was a leak in the ceiling above the autoclave about a week ago and the ceiling tile was removed. Interview confirmed the ceiling tile opening was located above the area where clean instruments were processed. Staff #3 stated she was not aware of a facility policy for cleaning or sterilizing surgical instruments. The staff member explained the procedure that she followed to sterilize surgical instruments. The process that she explained was consistent with the facility policy. The staff member stated there was no chemical indicator strip placed inside the instrument packs prior to sterilizing. The staff member stated she was taught to use the sterilizer tape on the outside of the pack to determine appropriate sterilization of the instruments. The staff member further stated there was no method of tracking the surgical instruments that were sterilized.	Q 144		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 144	Continued From page 30 Review of staff #3's personnel file revealed no evidence of training or competency checks regarding processing surgical instruments. Review revealed there was no personnel file and no evidence of training or competency checks regarding processing surgical instruments for staff #4. Interview on 07/19/2013 at 1430 with Physician A revealed staff #4 was a volunteer and there was no personnel file for staff #4. Interview confirmed the job responsibilities for staff #4 included processing the surgical instruments. Interview revealed staff #4 had no medical background and had not processed surgical instruments prior to volunteering at this facility. Interview revealed staff #4 was trained to process surgical instruments by a former employee. Interview confirmed there was no evidence of training or competency checks available. Interview on 07/19/2013 at 1545 with Physician A revealed she was not aware of a practice of using chemical indicators inside the surgical packs when sterilizing and did not use biological (spore) testing when sterilizing. The physician was not aware of a need to have a system in place for tracking surgical instruments when sterilizing the packs. Interview further reveled that the observation of the condensation on the sterile packs meant that the packs were removed from the sterilizer too soon and not allowed to dry properly. The physician stated she was not aware that it was a problem to have condensation inside the sterilized pack. The physician confirmed the facility's policy for sterilization of instruments had not been revised since 1989. The physician did not know what source or reference was used to develop the policy for	Q 144		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 144	Continued From page 31 sterilization and was not aware of using nationally recognized infection control guidelines for policy development. 2. Observation of the sterile processing area on 07/19/2013 at 1150 revealed clean supplies (scalpels and gauze) that were placed on the counter of the room next to the sink where dirty equipment is placed for cleaning after use. Interview with staff during the tour confirmed the finding. Interview on 07/19/2013 at 1545 with Physician A revealed that the clean surgical supplies that were observed on the counter next to the sink where the dirty instruments were placed was not appropriate and the staff should not be mixing the clean supplies with dirty instruments. The physician confirmed there were no policies regarding cross contamination of clean and dirty supplies. 3. Observation on 07/19/2013 at 1150 of a glucometer machine revealed a low control that expired 11/2009. Observation and staff interview revealed there were no high controls available. Interview with staff during the tour revealed the staff would use the machine if needed. Interview revealed the staff would wipe the machine down between patient use. Review of policies revealed no policy regarding the use and cleaning of the glucometer between patients. Interview on 07/19/2013 at 1545 with Physician A revealed there was no policy and procedure for care and use of the glucometer. The physician stated "I don't even know why it is here. We don't use it. We have the patient bring their machine from home if we need a glucometer." The physician confirmed the glucometer was located	Q 144		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 144	Continued From page 32 in the laboratory and available for patient use. 4. Observation on 07/18/2013 at 1730 revealed a Yankauer suction and suction tubing that was removed from the sterile packaging and left open in a drawer that was available for patient use. Interview with Physician A during the tour confirmed the finding. 5. Observation of the operating rooms (#1 and #2) on 07/19/2013 at 1150 revealed large amounts of dust that covered the tops of the suction machines and rolled up when touched. Observation revealed the top of the crash cart that was located in OR #1 revealed dust that rolled up when touched. Interview with staff during the tour confirmed the finding. Interview on 07/19/2013 at 1115 with staff #1 (registered nurse) revealed the staff member is a registered nurse (RN) that has worked at the facility since 2003. The nurse stated there was no infection control training provided at the facility. Interview on 07/19/2013 at 1545 with Physician A revealed there is no infection control program. The physician stated "We don't have any infection surveillance monitoring."	Q 144		
Q 145	.1302 STERILIZATION PROCEDURES 10A-13C.1302 (a) Policies and procedures shall be established in writing for storage, maintenance and distribution of sterile supplies and equipment. (b) Sterile supplies and equipment shall not be mixed with unsterile	Q 145		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 145	Continued From page 33 supplies, and shall be stored in dust proof and moisture free units. They shall be properly labeled. (c) Sterilizing equipment shall be available and of the necessary type and capacity to sterilize instruments and operating room materials, as well as laboratory equipment and supplies. The sterilizing equipment shall have design control and safety features intact. The accuracy of instrumentation and equipment shall be checked quarterly by any professionally recognized method and periodic calibration and preventive maintenance shall be provided as necessary, and a log maintained. (d) The date of expiration shall be marked on all supplies sterilized in the facility. This Rule is not met as evidenced by: Based on policy review, Centers for Disease Control and Prevention guidelines review, observation, personnel file reviews, staff and physician interview, the facility failed to maintain supplies and equipment for use in the surgical suite. The findings include: Review of "Operating of Pelton and Crane Autoclave" policy revised January 1989 revealed a procedure for steam sterilization of surgical instruments. Review of the policy revealed no procedure for the use of chemical or biological indicators during the sterilizing process. Review of the CDC (Centers for Disease Control and Prevention) Guidelines for Disinfection and	Q 145		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 145	Continued From page 34 Sterilization in Healthcare Facilities, 2008; Healthcare Infection Control Practices Advisory Committee (HICPAC) revealed "Sterilizing Practices Overview. The delivery of sterile products for use in patient care depends not only on the effectiveness of the sterilization process but also on the unit design, decontamination, disassembling and packaging of the device, loading the sterilizer, monitoring, sterilant quality and quantity, and the appropriateness of the cycle for the load contents, and other aspects of device reprocessing. ...Ensuring consistency of sterilization practices requires a comprehensive program that ensures operator competence and proper methods of cleaning and wrapping instruments, loading the sterilizer, operating the sterilizer, and monitoring of the entire process. ...Monitoring. The sterilization procedure should be monitored routinely by using a combination of mechanical, chemical, and biological indicators to evaluate the sterilizing conditions and indirectly the microbiologic status of the processed items. ... Chemical indicators are convenient, are inexpensive, and indicate that the item has been exposed to the sterilization process. Chemical indicators should be used in conjunction with biological indicators, but based on current studies should not replace them because they indicate sterilization at marginal sterilization time and because only a biological indicator consisting of resistant spores can measure the microbial killing power of the sterilization process847, 974. Chemical indicators are affixed on the outside of each pack to show that the package has been processed through a sterilization cycle, but these indicators do not prove sterilization has been achieved. Preferably, a chemical indicator also should be placed on the inside of each pack to verify sterilant penetration. ...Like other sterilization systems, the steam cycle is	Q 145		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 145	Continued From page 35 monitored by mechanical, chemical, and biological monitors. Steam sterilizers usually are monitored using a printout (or graphically) by measuring temperature, the time at the temperature, and pressure. Typically, chemical indicators are affixed to the outside and incorporated into the pack to monitor the temperature or time and temperature. The effectiveness of steam sterilization is monitored with a biological indicator containing spores of Geobacillus stearothermophilus (formerly Bacillus stearothermophilus). Positive spore test results are a relatively rare event 838 and can be attributed to operator error, inadequate steam delivery 839, or equipment malfunction. ...Sterile items that become wet are considered contaminated because moisture brings with it microorganisms from the air and surfaces...". Further review of the guidelines revealed "16. Monitoring of Sterilizers ...b. Monitor each load with mechanical (e.g., time, temperature, pressure) and chemical (internal and external) indicators. If the internal chemical indicator is visible, an external indicator is not needed. ... d. Use biological indicators to monitor the effectiveness of sterilizers at least weekly with an FDA-cleared commercial preparation of spores (e.g., Geobacillus stearothermophilus for steam) intended specifically for the type and cycle parameters of the sterilizer...." Observation on 07/18/2013 at 1810 during tour of the facility's sterile processing area revealed a ceiling tile (drop down ceiling) that was missing above the autoclave area where clean sterile packs were processed. The area was open to the pipes and air flow above the ceiling. Observation of the top of the autoclave revealed excessive dust that rolled up when touched. Interview during the tour with Physician A	Q 145		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 145	Continued From page 36 revealed the facility had a leak last week and the tile had to be removed. Interview confirmed the top of the autoclave was covered with a layer of dust. Observation on 07/18/2013 at 1815 revealed a cart with instrument packs located on the cart. Interview with Physician A during the tour revealed these packs were sterilized and available for use. Observation revealed three packs with beads of moisture located inside the clear packs. Physician A stated "Yes, there is condensation inside the packs. It will be okay tomorrow. I don't think there is a problem with that." Interview on 07/19/2013 at 0907 with staff #3 (non-licensed staff) revealed she was the person that was processing (sterilizing) the surgical instruments. Interview revealed staff #3 did not usually process the surgical instruments and was filling in for the regular person who was on vacation. Interview revealed the regular person that processed the surgical instruments was a volunteer (staff #4). Interview revealed staff #4 (volunteer) had been processing the instruments for about a year. Interview revealed staff #3 had been trained by staff #4 regarding how to process the instruments. Further interview revealed the staff member stated she "pulled the instruments out of the autoclave too early yesterday and caused the condensation." The staff member stated she was not aware that it was a problem to remove the packs before the drying cycle was completed and she was trying to get all of the packs done. Staff #3 revealed there was a leak in the ceiling above the autoclave about a week ago and the ceiling tile was removed. Interview confirmed the ceiling tile opening was located above the area where clean instruments were	Q 145		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 145	Continued From page 37 processed. Staff #3 stated she was not aware of a facility policy for cleaning or sterilizing surgical instruments. The staff member explained the procedure that she followed to sterilize surgical instruments. The process that she explained was consistent with the facility policy. The staff member stated there was no chemical indicator strip placed inside the instrument packs prior to sterilizing. The staff member stated she was taught to use the sterilizer tape on the outside of the pack to determine appropriate sterilization of the instruments. The staff member further stated there was no method of tracking the surgical instruments that were sterilized. Review of staff #3's personnel file revealed no evidence of training or competency checks regarding processing surgical instruments. Review revealed there was no personnel file and no evidence of training or competency checks regarding processing surgical instruments for staff #4. Interview on 07/19/2013 at 1430 with Physician A revealed staff #4 was a volunteer and there was no personnel file for staff #4. Interview confirmed the job responsibilities for staff #4 included processing the surgical instruments. Interview revealed staff #4 had no medical background and had not processed surgical instruments prior to volunteering at this facility. Interview revealed staff #4 was trained to process surgical instruments by a former employee. Interview confirmed there was no evidence of training or competency checks available. Interview on 07/19/2013 at 1545 with Physician A revealed she was not aware of a practice of using chemical indicators inside the surgical packs	Q 145		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 145	Continued From page 38 when sterilizing and did not use biological (spore) testing when sterilizing. The physician was not aware of a need to have a system in place for tracking surgical instruments when sterilizing the packs. Interview further reveled that the observation of the condensation on the sterile packs meant that the packs were removed from the sterilizer too soon and not allowed to dry properly. The physician stated she was not aware that it was a problem to have condensation inside the sterilized pack. The physician confirmed the facility's policy for sterilization of instruments had not been revised since 1989.	Q 145		
Q 146	.1303 HOUSEKEEPING 10A-13C.1303 Operating rooms shall be appropriately cleaned in accordance with established written procedures after each operation. Recovery rooms shall be maintained in a clean condition. This Rule is not met as evidenced by: Based on review of facility policy, review of a housekeeping contract, observation and physician and staff interview, the facility failed to ensure terminal cleaning of the operating rooms. The findings include: Review of an "Infection Control" policy revised 1992 revealed operating room floors are to be mopped daily and walls cleaned bi-weekly. Review of a "Cleaning Contract" signed 08/05/2003 revealed "Tuesday: ...Wipe down bottom or operating room beds; ... Sweep entire building; hallways, bathrooms, exam rooms,	Q 146		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	20130055	A. BUILDING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 146	Continued From page 39 kitchen and operating room area; ... Mop entire building with germicide; ... Miscellaneous indoor cleaning: ...Wipe down walls in operating rooms every other week; Dust and clean light fixtures bi-monthly or as needed." Observation on 07/18/2013 at 1740 during tour of the operating room #1 revealed a thick layer of dust that rolled up when touched that was covering the top of the crash cart that was located in the operating room (OR). Observation further revealed a thick layer of dust on the surface of the suction machine and nitrous oxide machine located in the OR. Observation revealed a thick layer of dust located on the surface of the suction machine and nitrous oxide machine in OR #2. Physician A confirmed the observation. Interview on 07/19/2013 at 0907 with staff #3 (non-licensed staff) revealed the facility staff clean between patients including wiping down the operating room beds and any blood spills. Interview revealed the staff do not mop floors between patients. Interview revealed surgical procedures are scheduled on Wednesdays, Fridays and Saturdays. The staff member stated there was a person that comes to the facility on Tuesday evenings that does the "big cleaning" including mopping. Staff #3 stated housekeeping comes on Wednesday and Friday evenings, but the staff member was unsure if the floors are mopped on those days. Interview on 07/19/2013 at 1440 with Physician A revealed the physician did not know if terminal cleaning of the operating rooms was being done. Interview revealed the physician did not know how often floors were being mopped in the operating rooms. Interview confirmed there was no documentation of terminal cleaning of the	Q 146		

STATEMENT OF OEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIOER/SUPPLIER/CLIA IOENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) OATE SURVEY COMPLETED
	20130055	A. BUILOING: _____ B. WING _____	07/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET AODRESS, CITY, STATE, ZIP CODE
FEMCARE, INC	63 ORANGE STREET ASHEVILLE, NC 28801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Q 146	Continued From page 40 operating rooms and no monitoring of housekeeping duties. Interview confirmed there was a think layer of dust located on the equipment and horizontal surfaces in the operating rooms. Interview revealed the physician did not know if the housekeeping staff had any training in infection control prevention.	Q 146		